



[3510-16-P]

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

37 CFR Part 1

Docket No. PTO-P-2011-0072

RIN 0651-AC66

Changes to Implement Miscellaneous Post Patent Provisions of the Leahy-Smith America Invents Act

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Leahy-Smith America Invents Act expands the scope of information that any party may cite in a patent file, to include written statements made by a patent owner before a Federal court or the United States Patent and Trademark Office (Office) regarding the scope of any claim of the patent, and it provides for how such information may be considered in ex parte reexamination, inter partes review, and post grant review. The Leahy-Smith America Invents Act also provides for an estoppel that may attach with

respect to ex parte reexamination based on an inter partes review or post grant review proceeding. The Office is revising the rules of practice to implement these post-patent provisions, as well as other miscellaneous provisions of the Leahy-Smith America Invents Act.

COMMENT DEADLINE DATE: To be ensured of consideration, written comments must be received on or before [Insert date 60 days after publication in the FEDERAL REGISTER].

ADDRESSES: Comments should be sent by electronic mail addressed to: post_patent_provisions@uspto.gov. Comments may also be submitted by mail addressed to: Mail Stop Comments--Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA, 22313-1450, marked to the attention of Kenneth M. Schor, Senior Legal Advisor, Office of Patent Legal Administration, Office of the Associate Commissioner for Patent Examination Policy.

Comments may also be sent by electronic mail message over the Internet via the Federal eRulemaking Portal. See the Federal eRulemaking Portal Web site (<http://www.regulations.gov>) for additional instructions on providing comments via the Federal eRulemaking Portal.

Although comments may be submitted by postal mail, the Office prefers to receive comments by electronic mail message over the Internet because sharing comments with the public is more easily accomplished. Electronic comments are preferred to be submitted in plain text, but also may be submitted in ADOBE® portable document format or MICROSOFT WORD® format. Comments not submitted electronically should be submitted on paper in a format that facilitates convenient digital scanning into ADOBE® portable document format.

The comments will be available for public inspection at the Office of the Commissioner for Patents, currently located in Madison East, Tenth Floor, 600 Dulany Street, Alexandria, Virginia. Comments also will be available for viewing via the Office's Internet Web site (<http://www.uspto.gov>). Because comments will be made available for public inspection, information that the submitter does not desire to make public, such as an address or phone number, should not be included in the comments.

FOR FURTHER INFORMATION CONTACT: Kenneth M. Schor, Senior Legal Advisor ((571) 272-7710), or Joseph F. Weiss, Jr., Legal Advisor ((571) 272-7759), Office of Patent Legal Administration, Office of the Associate Commissioner for Patent Examination Policy.

SUPPLEMENTARY INFORMATION: Section 6 of the Leahy-Smith America Invents Act replaces the current inter partes reexamination proceedings with inter partes review proceedings, and creates new post grant review proceedings. See Pub. L. 112-29, 125 Stat. 284 (2011). Section 6 of the Leahy-Smith America Invents Act also provides for an estoppel that may attach with respect to ex parte reexamination based on an inter partes review or post grant review proceeding. The Office is proposing to revise the rules of practice in title 37 of the Code of Federal Regulations (CFR) to implement these post-patent provisions, along with changes in nomenclature pertaining to the renaming of the “Board of Patent Appeals and Interferences” as the “Patent Trial and Appeal Board” and the replacement of references to interference proceedings with references to derivation proceedings. The post grant review, inter partes review, and derivation provisions of sections 3 and 6 of the Leahy-Smith America Invents Act will be implemented by separate rulemakings.

I. Background.

Section 6(g) of the Leahy-Smith America Invents Act amends 35 U.S.C. 301 to expand the information that can be submitted in the file of an issued patent by including written statements made by a patent owner before a Federal court or the Office regarding the scope of any claim of the patent. The provision limits the Office’s use of such written statements to determining the meaning of a patent claim in ex parte reexamination proceedings that have already been ordered and in inter partes review and post grant

review proceedings that have been instituted. This provision is effective on September 16, 2012.

Section 6(a) and (d) of the Leahy-Smith American Invents Act also contains provisions in new 35 U.S.C. 315(e)(1) and 35 U.S.C. 325(e)(1) for estopping a third party requester from filing a request for ex parte reexamination, in certain instances where the third party requester filed a petition for inter partes review or post grant review and a final written decision under 35 U.S.C. 318(a) or 35 U.S.C. 328(a) has been issued. In addition, a third party requester may not maintain an ex parte reexamination if the estoppel provisions are met during the pendency of the ex parte reexamination proceeding. The estoppel provisions apply to the real party(ies) in interest of the inter partes review or post grant review petitioner and any privy of such a petitioner. This provision is effective on September 16, 2012.

In view of the estoppel provisions, the Office needs to be aware of any final written decision in an inter partes review or post grant review regarding the patentability of claims. Current § 1.565(a) requires the patent owner to “inform the Office of any prior or concurrent proceedings in which the patent is or was involved such as interferences, reissues, ex parte reexaminations, inter partes reexaminations, or litigation and the results of such proceedings.” Because current § 1.565(a) uses open language to provide a non-exhaustive listing of proceedings that patent owner must inform the Office about, the current rule will include inter partes review and post grant review proceedings, once they

become effective. In addition, the third party requester (to whom the inter partes review or post grant review estoppel statutes are directed) may inform the Office of a final written decision in an inter partes review or post grant review of the patent subject to the ex parte reexamination by filing a “Notification of Existence of Prior or Concurrent Proceedings and Decisions Thereon” pursuant to Manual of Patent Examining Procedure (MPEP) § 2282 (8th ed. 2001) (Rev. 8, July 2010). MPEP § 2282 provides that “in order to ensure a complete file, with updated status information regarding prior or concurrent proceedings regarding the patent under reexamination, the Office will, at any time, accept from any parties, for entry into the reexamination file, copies of notices of suits and other proceedings involving the patent and copies of decisions or papers filed in the court from litigations or other proceedings involving the patent.” [Emphasis added]

Section 6(h)(1) of the Leahy-Smith America Invents Act amends 35 U.S.C. 303 to expressly identify the authority of the Director to initiate reexamination based on patents and publications cited in a prior reexamination request under 35 U.S.C. 302, as well as on those cited under 35 U.S.C. 301 (which was previously expressly authorized). This provision is effective on September 16, 2012.

Section 3(i) of the Leahy-Smith America Invents Act replaces interference proceedings with derivation proceedings; section 3(j) replaces the title “Board of Patent Appeals and Interferences” with “Patent Trial and Appeal Board” in 35 U.S.C. 134, 145, 146, 154, and 305; Section 6(a) replaces inter partes reexamination with inter partes review of a patent;

Section 6(d) provides for post-grant review of patents; and Section 7 amends 35 U.S.C. 6(b) to define the duties of the Patent Trial and Appeal Board.

II. Discussion of Specific Rules:

Title 37 of the Code of Federal Regulations, Part 1, is proposed to be amended as follows:

The undesignated center heading before § 1.501: It is proposed that the undesignated center heading be revised to read “Citation of prior art and written statements.”

Section 1.501: Proposed § 1.501 is rewritten to reflect the amendment to 35 U.S.C. 301 by section 6(g)(1) of the Leahy-Smith America Invents Act. New 35 U.S.C. 301(a)(2) would permit a submission under 35 U.S.C. 301 and §1.501 to contain, in addition to prior art (currently provided for in §1.501), “statements of the patent owner filed in a proceeding before a Federal court or the Office in which the patent owner took a position on the scope of any claim of a particular patent” (claim scope statements of the patent owner). Proposed § 1.501 provides that a submission can include prior art and claim scope statements of the patent owner. The term “Federal court” in 35 U.S.C. 301(a)(2) is understood to also include the United States Court of International Trade.

Section 1.501(a): Proposed § 1.501(a)(1), like current § 1.501(a), provides for submission to the Office of prior art directed to patents or printed publications allegedly bearing on the patentability of any claim of a particular patent. Section 1.501(a)(2) newly permits submission of statements of the patent owner filed in a proceeding before a Federal court or the Office in which the patent owner took a position on the scope of any claim of a patent (claim scope statements). Any statement submitted under this paragraph must be accompanied by any other documents, pleadings, or evidence from the proceeding in which the statement was filed that address the statement; and the statement and accompanying information under this paragraph must be submitted in redacted form to exclude information subject to an applicable protective order. For example, a third party may submit a deposition of the patent owner occurring during the course of the Federal court proceeding where the patent owner discusses the scope of a patent claim. A party submitting any submission that includes § 1.501(a)(2) information should also consider providing the following information to assist the Office in identifying the proceeding where the patent owner claim scope statement was made: (1) the forum in which the statement was made (the specific Federal court or the Office); (2) the Federal court or Office proceeding designation (case citation or numerical designation); (3) the status of the proceeding; (4) the relationship of the proceeding to the patent in which the submission is being made; (5) an identification of the specific papers of the proceeding containing the statement of the patent owner; and (6) an identification of the portion(s) of the papers relevant to the written statement being asserted to constitute a statement of the patent owner under 35 U.S.C. 301(a)(2). Any patent owner statement regarding the

scope of any claim of a particular patent made outside of a Federal court or Office proceeding is not a written statement eligible for submission under 35 U.S.C. 301(a)(2), even though it may be later entered into a Federal court or Office proceeding by a party other than the patent owner. See H.R. Rep. No. 112-98, Part 1, at page 46 (2011) (“[t]his addition will counteract the ability of patent owners to offer differing interpretations of prior art in different proceedings”).

Section 1.501(b): Proposed § 1.501(b)(1) is directed to the 35 U.S.C. 301(b) requirement that the submission include an explanation “in writing [of] the pertinency and manner of applying the prior art or written statements” to at least one patent claim. Proposed § 1.501(b)(1) requires an explanation as to how the information in the submission is pertinent to the claim(s) of the patent and how it is applied to each of those claims. In some instances, a combination of prior art and written statements may be cited, while in other situations only prior art or written statements may be cited. In either situation, an explanation as to how the cited information applies to those specific claims must be included with the submission of patent owner statements under 35 U.S.C. 301(a)(2). Section 1.501(b)(1) requires an explanation of the additional information required by 35 U.S.C. 301(c) (as a result of the Leahy-Smith America Invents Act), because the additional information addresses and provides context to the written statement of the patent owner; thus, it provides an additional explanation as to how the cited information is pertinent to the claim(s).

Proposed § 1.501(b)(2) is directed to the substance of the second sentence of current § 1.501(a), which provides regulatory authorization for a patent owner submitter to include an explanation of how the claims differ from the prior art submitted. Proposed § 1.501(b)(2) simply adds statements of patent owner under 35 U.S.C. 301(a)(2) to the current regulatory authorization.

Section 1.501(c): Proposed § 1.501(c) restates the last sentence of existing § 1.501(a) directed to the timing for a submission under §§ 1.502 and 1.902 when there is a reexamination proceeding pending for the patent in which the submission is made. Pursuant to current §§ 1.502 and 1.902, entry (into the official patent file) of a proper submission that is made after the date of an order to reexamine will be delayed (with certain exceptions specified in §§ 1.502 and 1.902) until the reexamination proceeding has been concluded by the issuance and publication of a reexamination certificate. This prevents harassment of the patent owner by frequent submissions of prior art made during a reexamination proceeding, as well as unwarranted interruption and delay of the reexamination proceeding, which would be contrary to the mandate under 35 U.S.C. 305 and 35 U.S.C. 314(c) that all reexamination proceedings are to be “conducted with special dispatch within the Office.”

Section 1.501(d): Proposed § 1.501(d) restates existing § 1.501(b), to permit the person making the submission to exclude his or her identity from the patent file by anonymously filing the submission.

Section 1.501(e): Proposed § 1.501(e) requires that a submission made under § 1.501 must reflect that a copy of the submission has been served upon the patent owner at the correspondence address of record in the patent, and that service was carried out in accordance with § 1.248. Service is required to provide notice to the patent owner of the submission. The presence of a certificate of service compliant with § 1.248(b) is prima facie evidence of compliance with § 1.501(e). If service upon patent owner is unsuccessful, the submission must include proof of a bona fide attempt to serve. Proof of a bona fide attempt to serve must include a statement of facts with an explanation of the inability to serve the submission upon patent owner, along with all supporting evidence of the attempt of service. The statement of facts must be signed by a person having firsthand knowledge of the facts recited, regarding unsuccessful service. The statement of facts should include the steps taken to locate and serve the patent owner. A statement of facts which provides a mere conclusion or assertion of unsuccessful service will not satisfy this requirement. Copies of documentary proof such as certified/registered mail receipts, cover letters, telegrams or other forms of evidence that support a finding that the patent owner could not be served should be made part of the statement of facts. A submission will not be entered into the patent's Image File Wrapper (IFW) if it does not include either proof of service compliant with § 1.248(b) or a sufficient explanation and proof of a bona fide attempt of service, and if such a submission is inadvertently entered, it will be expunged. Where a submission complies with the rule, all information included in the submission will be made of record in the IFW of the patent. A best practice for

patent owners is to regularly monitor the IFW record of their patents in the event that a third party was unsuccessful in serving the patent owner at the correspondence address of record. Such regular monitoring allows a patent owner to be aware of all information added to its patent files.

Section 1.501(f): Proposed § 1.501(f) limits the use of statements of the patent owner and accompanying information submitted under § 1.501(a)(2) to what is provided for in 35 U.S.C. 301(d). Thus, statements of the patent owner and accompanying information submitted under paragraph (a)(2) may only be used for determination of the proper meaning of a patent claim in: (1) an ex parte reexamination proceeding that has been ordered pursuant to 35 U.S.C. 304; (2) an inter partes review proceeding that has been instituted pursuant to 35 U.S.C. 314; and (3) a post grant review proceeding that has been instituted pursuant to 35 U.S.C. 324. Proposed § 1.501(f) follows from new 35 U.S.C. 301(d), which provides that “a written statement submitted pursuant to subsection (a)(2)” “shall not be considered by the Office for any purpose other than to determine the proper meaning of a patent claim in a proceeding that is ordered or instituted pursuant to section 304, 314, or 324.” The reference to 35 U.S.C. 314 is understood to apply to inter partes review, and not to inter partes reexamination, because inter partes reexamination is being replaced by inter partes review on the date that 35 U.S.C. 301(d) becomes effective (i.e., September 16, 2012). While inter partes reexamination proceedings already ordered will continue after September 16, 2012, 35 U.S.C. 314 is understood not to apply to such proceedings.

Section 1.510: Proposed § 1.510(b)(2) is revised, and new §§ 1.510(b)(6) and (b)(7) are added to implement provisions of the Leahy-Smith America Invents Act. Section 1.510(b)(2) is revised to require that a request for reexamination identify every claim for which reexamination is requested, and for any statement of the patent owner submitted pursuant to § 1.501(a)(2) which is relied upon in the detailed explanation, explain how that statement is being used to determine the proper meaning of a patent claim in connection with prior art applied to that claim. New 35 U.S.C. 301(d) provides that a statement of the patent owner, pursuant to § 1.501(a)(2), may be relied upon in the ex parte reexamination proceeding only after reexamination has been ordered. In order to comply with the requirement of 35 U.S.C. 302 that the “request must set forth the pertinency and manner of applying cited prior art to every claim for which reexamination is requested,” the “detailed explanation” provided in the request (pursuant to § 1.510(b)(2)) must explain how each § 1.501(a)(2) statement is being used to determine the proper meaning of a patent claim in connection with the applied prior art. This must be explained for each claim for which the § 1.501(a)(2) statement is being used in the request, and the explanation will be considered by the Office during the examination stage, if reexamination is ordered. At the order stage, the Office will use the broadest reasonable interpretation of the claims, without consideration to any § 1.501(a)(2) statement relied upon in the detailed explanation of a request.

New § 1.510(b)(6) requires that the request contain a certification that the statutory estoppel provisions of inter partes review and post grant review do not bar the third party from requesting ex parte reexamination. To complement this revision, § 1.510(b)(7) requires that the request contain, as part of the certification, a statement identifying the real party(ies) in interest to the extent necessary to determine whether an inter partes review or post grant review filed subsequent to an ex parte reexamination bars the third party from maintaining a pending ex parte reexamination. An ex parte reexamination requester has the option to remain anonymous. In order to do so, the requester must:

- (1) submit the statement identifying the real party(ies) in interest as a separate paper;
- (2) title the paper as a statement identifying the real party(ies) in interest;
- (3) request in the paper that the Office to retain the paper in confidence by sealing it; and
- (4) include, in a clear and conspicuous manner, an appropriate instructional label designating the statement as a non-public submission, e.g., NOT OPEN TO THE PUBLIC FOR OFFICE USE ONLY. The Office will then maintain the real party(ies) in interest statement as a sealed, non-public submission.

The estoppel provisions of inter partes review and post grant review are provided in new 35 U.S.C. 315(e)(1) and 325(e)(1), respectively. These estoppel provisions bar a request for ex parte reexamination (or maintenance of an ex parte reexamination) by a third party requester, the requester's real party(ies) in interest, or a privy, where the requester petitioned for an inter partes review or post grant review of a claim in the patent that resulted in a final written decision with respect to that claim on any ground that the

petitioner raised or reasonably could have raised during that inter partes review or post grant review. The certification and identification in new §§ 1.510(b)(6) and 1.510(b)(7) are consistent with the practice of real party(ies) in interest identification certification used for existing inter partes reexamination. As was the case for implementation of §§ 1.915(b)(7) and 1.915(b)(8) for inter partes reexamination, the certification and identification to be implemented via new §§ 1.510(b)(6) and 1.510(b)(7) address Congress's desire to prevent harassment of the patent owner by third parties. See H.R. Rep. No. 112-98 (Part 1), at 48.

Section 1.515: Section 1.515 is revised to add: "A statement pursuant to § 1.501(a)(2) will not be considered by the examiner in the examiner's determination on the request." New 35 U.S.C. 301(d) states: "A written statement submitted pursuant to subsection (a)(2), and additional information submitted pursuant to subsection (c) [of 35 U.S.C. 301], shall not be considered by the Office for any purpose other than to determine the proper meaning of a patent claim in a proceeding that is ordered ... pursuant to section 304." The Office interprets 35 U.S.C. 301(d) as prohibiting it from considering a § 1.501(a)(2) written statement when making the determination of whether to order ex parte reexamination under 35 U.S.C. 303. See also H.R. Rep. No. 112-98, Part 1, at page 46 (2011). In making the § 1.515(a) determination of whether to order ex parte reexamination, the Office will generally (except in the rare case of an expired patent), give the claims the broadest reasonable interpretation consistent with the specification (See In re Yamamoto, 740 F.2d 1569, 222 USPQ 934 (Fed. Cir. 1984)). Consideration of

the evidentiary weight to be accorded to a 35 U.S.C. 301 (a)(2) statement (as to the meaning of the claims with respect to the ultimate patentability decision) will not be given unless reexamination is ordered. If reexamination is ordered, the patent owner statements submitted pursuant to 35 U.S.C. 301(a)(2) will be considered to the fullest extent possible when determining the scope of any claims in the patent which are subject to reexamination.

Section 1.552: § 1.552 is rewritten to include new subsection § 1.552(d) to reflect the amendment of 35 U.S.C. 301 by section 6(g)(1) of the Leahy-Smith America Invents Act. Proposed § 1.552(d) states: “Any statement of the patent owner and any accompanying information submitted pursuant to § 1.501(a)(2) which is of record in the patent being reexamined (which includes any reexamination files for the patent) may be used after a reexamination proceeding has been ordered to determine the proper meaning of a patent claim when applying patents or printed publications.” New 35 U.S.C. 301(a)(2) permits a submission under 35 U.S.C. 301 to contain “statements of the patent owner filed in a proceeding before a Federal court or the Office in which the patent owner took a position on the scope of any claim of a particular patent.” Thus, written statements cited under new 35 U.S.C. 301(a)(2) may be considered after an ex parte reexamination proceeding has been ordered, but not in making the determination of whether to order ex parte reexamination under 35 U.S.C. 303. See 35 U.S.C. 301(d). See also H.R. Rep. No. 112-98, Part 1, at page 46 (2011).

The Office also proposes to change the nomenclature in title 37 CFR to reflect renaming the “Board of Patent Appeals and Interferences” as the “Patent Trial and Appeal Board,” including changes for the new trial proceedings of inter partes review, post grant review, and derivation. Specifically, the Office proposes to change “Board of Patent Appeals and Interferences” to the “Patent Trial and Appeal Board” in 37 CFR parts 1, 11, and 41 (in §§ 1.1(a)(1)(ii), 1.4(a)(2), 1.6(d)(9), 1.8(a)(2)(i)(C), 1.9(g), 1.17(b), 1.36(b), 1.48(j), 1.136(a)(1)(iv), 1.136(a)(2), 1.136(b), 1.181(a)(1), 1.181(a)(3), 1.191, 1.197(a), 1.198, 1.248(c), 1.294(b), 1.301, 1.303(a), 1.304(a)(1), 1.304(a)(1)(ii), 1.324(d), 1.550(a), 1.701(a)(3), 1.701(c)(3), 1.702(a)(3), 1.702(b)(4), 1.702(e), 1.703(a)(5), 1.703(b)(4), 1.703(e), 1.704(c)(9), 1.937(a), 1.959, 1.979(a), 1.979(b), 1.981, 1.983(a), 1.983(c), 1.983(d), 1.983(f), 11.5(b)(1), 11.6(d), 41.1(a), 41.2, 41.10(a)-(c), and 41.77(a), and in the title of part 41). The Office likewise proposes to add specific references to trial proceedings before the Patent Trial and Appeal Board to §§ 1.5(c), 1.6(d), 1.6(d)(9), 1.11(e), 1.136(a)(2), 1.136(b), 1.178(b), 1.248(c), 1.322(a)(3), 1.324(a), 1.324(d), 1.565(a), 1.565(e), 1.985(a), 1.985(b), 1.993, 10.1(s), 11.10(b)(3)(iii), and 11.57(b)(1)(i). Finally, the Office proposes to add specific references to derivation proceedings to §§ 1.48(j), 1.55(a)(3)(i), 1.55(a)(4)(i)(A), 1.103(g), 1.136(a)(1)(v), 1.313(b)(4), 1.701(a)(1), 1.701(c)(1)(i-ii), 1.701(c)(2)(iii), 1.702(b)(2), 1.702(c), 1.703(b)(2)(i-ii), 1.703(b)(3)(iii), 1.703(c)(1-2), 1.703(d)(3), and 5.3(b).

III. Rulemaking Considerations

A. Administrative Procedure Act (APA): This proposed rule revises existing rules governing prior art citations and patent owner statements in a patent file and ex parte reexamination to implement the following provisions of sections 3 and 6 of the Leahy-Smith America Invents Act: (1) section 6(g) which amends 35 U.S.C. 301, to expand the scope of information that can be submitted in the file of an issued patent; (2) the provisions of sections 6(a) and 6(d) (which newly enact inter partes review and post grant review, respectively) that provide for estoppels effective as to proceedings before the Office, including but not limited to reexamination; and (3) sections 3(j) and 7 which change the title “Board of Patent Appeals and Interferences” to “Patent Trial and Appeal Board,” and change references to interference proceedings to derivation proceedings.

Therefore, the changes in this proposed rule are merely procedural and/or interpretive. See Bachow Communs., Inc. v. FCC, 237 F.3d 683, 690 (D.C. Cir. 2001) (rules governing an application process are procedural under the Administrative Procedure Act); Inova Alexandria Hosp. v. Shalala, 244 F.3d 242, 350 (4th Cir. 2001) (rules for handling appeals were procedural where they did not change the substantive standard for reviewing claims); Nat’l Org. of Veterans’ Advocates v. Sec’y of Veterans Affairs, 260 F.3d 1365, 1375 (Fed. Cir. 2001) (rule that clarifies interpretation of a statute is interpretive).

Accordingly, prior notice and opportunity for public comment are not required pursuant to 5 U.S.C. 553(b) or (c) (or any other law) and thirty-day advance publication is not

required pursuant to 5 U.S.C. 553(d) (or any other law). See Cooper Techs. Co. v. Dudas, 536 F.3d 1330, 1336-37 (Fed. Cir. 2008) (stating that 5 U.S.C. 553, and thus 35 U.S.C. 2(b)(2)(B), does not require notice and comment rulemaking for “interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice.”) (quoting 5 U.S.C. 553(b)(A)). The Office, however, is publishing these changes for comment as it seeks the benefit of the public’s views on the Office’s proposed implementation of these provisions of the Leahy-Smith America Invents Act.

B. Regulatory Flexibility Act: As prior notice and an opportunity for public comment are not required pursuant to 5 U.S.C. 553 or any other law, neither a regulatory flexibility analysis nor a certification under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.) is required. See 5 U.S.C. 603.

C. Executive Order 12866 (Regulatory Planning and Review): This rulemaking has been determined to be not significant for purposes of Executive Order 12866 (Sept. 30, 1993).

D. Executive Order 13563 (Improving Regulation and Regulatory Review): The Office has complied with Executive Order 13563. Specifically, the Office has, to the extent feasible and applicable: (1) made a reasoned determination that the benefits justify the costs of the rule; (2) tailored the rule to impose the least burden on society consistent with obtaining the regulatory objectives; (3) selected a regulatory approach

that maximizes net benefits; (4) specified performance objectives; (5) identified and assessed available alternatives; (6) involved the public in an open exchange of information and perspectives among experts in relevant disciplines, affected stakeholders in the private sector and the public as a whole, and provided on-line access to the rulemaking docket; (7) attempted to promote coordination, simplification, and harmonization across government agencies and identified goals designed to promote innovation; (8) considered approaches that reduce burdens and maintain flexibility and freedom of choice for the public; and (9) ensured the objectivity of scientific and technological information and processes.

E. Executive Order 13132 (Federalism): This rulemaking does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under Executive Order 13132 (Aug. 4, 1999).

F. Executive Order 13175 (Tribal Consultation): This rulemaking will not: (1) have substantial direct effects on one or more Indian tribes; (2) impose substantial direct compliance costs on Indian tribal governments; or (3) preempt tribal law. Therefore, a tribal summary impact statement is not required under Executive Order 13175 (Nov. 6, 2000).

G. Executive Order 13211 (Energy Effects): This rulemaking is not a significant energy action under Executive Order 13211 because this rulemaking is not likely to have

a significant adverse effect on the supply, distribution, or use of energy. Therefore, a Statement of Energy Effects is not required under Executive Order 13211 (May 18, 2001).

H. Executive Order 12988 (Civil Justice Reform): This rulemaking meets applicable standards to minimize litigation, eliminate ambiguity, and reduce burden as set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 (Feb. 5, 1996).

I. Executive Order 13045 (Protection of Children): This rulemaking does not concern an environmental risk to health or safety that may disproportionately affect children under Executive Order 13045 (Apr. 21, 1997).

J. Executive Order 12630 (Taking of Private Property): This rulemaking will not effect a taking of private property or otherwise have taking implications under Executive Order 12630 (Mar. 15, 1988).

K. Congressional Review Act: Under the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.), prior to issuing any final rule, the United States Patent and Trademark Office will submit a report containing the final rule and other required information to the United States Senate, the United States House of Representatives, and the Comptroller General of the Government Accountability Office. The changes in this notice are not expected to result

in an annual effect on the economy of 100 million dollars or more, a major increase in costs or prices, or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. Therefore, this notice is not expected to result in a “major rule” as defined in 5 U.S.C. 804(2).

L. Unfunded Mandates Reform Act of 1995: The changes proposed in this notice do not involve a Federal intergovernmental mandate that will result in the expenditure by State, local, and tribal governments, in the aggregate, of 100 million dollars (as adjusted) or more in any one year, or a Federal private sector mandate that will result in the expenditure by the private sector of 100 million dollars (as adjusted) or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions are necessary under the provisions of the Unfunded Mandates Reform Act of 1995. See 2 U.S.C. 1501 et seq.

M. National Environmental Policy Act: This rulemaking will not have any effect on the quality of the environment and is thus categorically excluded from review under the National Environmental Policy Act of 1969. See 42 U.S.C. 4321 et seq.

N. National Technology Transfer and Advancement Act: The requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995

(15 U.S.C. 272 note) are not applicable because this rulemaking does not contain provisions which involve the use of technical standards.

O. Paperwork Reduction Act: The Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.) requires that the Office consider the impact of paperwork and other information collection burdens imposed on the public. This proposed rulemaking involves information collection requirements which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3549). The collection of information involved in this notice has been submitted to OMB under OMB control number 0651-00xx. The proposed collection will be available at OMB's Information Collection Review Web site (www.reginfo.gov/public/do/PRAMain).

Needs and Uses: This information collection is necessary so that the public may file, in a patent, submissions of patents and printed publications, and statements of the patent owner filed in a proceeding before a Federal court or the Office in which the patent owner took a position on the scope of any claim of the patent. The public may use this information to aid in ascertaining the patentability and/or scope of the claims of the patent.

Title of Collection: Post Patent Public Submissions.

OMB Control Number: 0651-00xx.

Method of Collection: By mail, facsimile, hand delivery, or electronically to the Office.

Affected Public: Individuals or households; businesses or other for-profits; and not-for-profit institutions.

Estimated Number of Respondents: 1,000 responses per year.

Estimated Time Per Response: The Office estimates that the responses in this collection will take the public 10 hours.

Estimated Total Annual Respondent Burden Hours: 10,000 hours per year.

Estimated Total Annual Respondent Cost Burden: \$3,400,000 per year.

The Office is soliciting comments to: (1) evaluate whether the proposed information requirement is necessary for the proper performance of the functions of the Office, including whether the information will have practical utility; (2) evaluate the accuracy of the Office's estimate of the burden; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of collecting the information on those who are to respond, including by using appropriate automated, electronic,

mechanical, or other technological collection techniques or other forms of information technology.

Please send comments on or before [Insert date 60 days after publication in the FEDERAL REGISTER] to Mail Stop Comments--Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA, 22313-1450, marked to the attention of Raul Tamayo, Legal Advisor, Office of Patent Legal Administration, Office of the Associate Commissioner for Patent Examination Policy. Comments should also be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10202, 725 17th Street, N.W., Washington, DC 20503, Attention: Desk Officer for the Patent and Trademark Office.

Notwithstanding any other provision of law, no person is required to respond to, nor shall a person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act, unless that collection of information displays a currently valid OMB control number.

List of Subjects

37 CFR Part 1

Administrative practice and procedure, Courts, Freedom of information, Inventions and patents, Reporting and record keeping requirements, Small businesses, and Biologics.

For the reasons set forth in the preamble, 37 CFR Part 1 is proposed to be amended as follows:

PART 1 - RULES OF PRACTICE IN PATENT CASES

1. The authority citation for 37 CFR Part 1 continues to read as follows:

Authority: 35 U.S.C. 2(b)(2), unless otherwise noted.

2. The undesignated center heading before § 1.501 is revised to read as follows:

CITATION OF PRIOR ART AND WRITTEN STATEMENTS

3. Section 1.501 is revised to read as follows:

§ 1.501 Citation of prior art and written statements in patent files.

(a) Information content of submission: At any time during the period of enforceability of a patent, any person may file a written submission with the Office under this section, which is directed to the following information:

(1) Prior art consisting of patents or printed publications which the person making the submission states to have a bearing on the patentability of any claim of the patent; or

(2) Statements of the patent owner filed in a proceeding before a Federal court or the Office in which the patent owner took a position on the scope of any claim of the patent. Any statement submitted under this paragraph must be accompanied by any other documents, pleadings, or evidence from the proceeding in which the statement was filed that address the written statement, and such statement and accompanying information under this paragraph must be submitted in redacted form to exclude information subject to an applicable protective order. Submission of a statement of the patent owner made outside of a Federal court or Office proceeding and later filed for inclusion in a Federal court or Office proceeding is not permitted by this section, and such a submission will not be entered into the patent file.

(b) Explanation included: A submission pursuant to paragraph (a) of this section:

(1) Must explain in writing the pertinence and manner of applying any prior art submitted under paragraph (a)(1) of this section and any written statement and accompanying information submitted under paragraph (a)(2) of this section to at least one claim of the patent, in order for the submission to become a part of the official file of the patent; and

(2) May, if the submission is made by the patent owner, include an explanation of how the claims differ from any prior art submitted under paragraph (a)(1) of this section or any written statements and accompanying information submitted under paragraph (a)(2) of this section.

(c) Reexamination pending: If a reexamination proceeding has been requested and is pending for the patent in which the submission is filed, entry of the submission into the official file of the patent is subject to the provisions of §§ 1.502 and 1.902.

(d) Identity: If the person making the submission wishes his or her identity to be excluded from the patent file and kept confidential, the submission papers must be submitted anonymously without any identification of the person making the submission.

(e) Service of the submission: A submission made under this section must reflect that a copy of the submission has been served upon the patent owner at the correspondence address of record in the patent, in accordance with § 1.248, or that a bona fide attempt of service was made. A submission that fails to include either proof of service or a sufficient explanation and proof of a bona fide attempt of service will not be entered into the patent file, and will be expunged if inadvertently entered.

(f) Consideration of statements of patent owner: Statements of the patent owner and accompanying information submitted under paragraph (a)(2) of this section shall not be considered by the Office for any purpose other than as provided for in 35 U.S.C. 301(d) . If reexamination is ordered, the patent owner statements submitted pursuant to section 301(a)(2) will be considered when determining the scope of any claims in the patent subject to reexamination.

4. Section 1.510 is amended by revising paragraph (b)(2), and adding new paragraphs (b)(6) and (b)(7), to read as follows:

§ 1.510 Request for ex parte reexamination.

* * * * *

(b) * * *

(2) An identification of every claim for which reexamination is requested, and a detailed explanation of the pertinency and manner of applying the cited prior art to every claim for which reexamination is requested. For each statement and accompanying information of the patent owner submitted pursuant to § 1.501(a)(2) which is relied upon in the detailed explanation, the request must explain how that statement is being used to determine the proper meaning of a patent claim in connection with the prior art applied to that claim and how each relevant claim is being interpreted. If appropriate, the party requesting reexamination may also point out how claims distinguish over cited prior art.

* * * * *

(6) A certification that the statutory estoppel provisions of both inter partes review (35 U.S.C. 315(e)(1)) and post grant review (35 U.S.C. 325(e)(1)) do not prohibit the ex parte reexamination.

(7) A statement identifying the real party(ies) in interest to the extent necessary to determine whether any inter partes review or post grant review filed subsequent to an ex parte reexamination bars a pending ex parte reexamination filed by the real party(ies) in interest or its privy from being maintained.

5. Section 1.515 is amended by revising paragraph (a) to read as follows:

§ 1.515 Determination of the request for ex parte reexamination.

(a) Within three months following the filing date of a request for an ex parte reexamination, an examiner will consider the request and determine whether or not a substantial new question of patentability affecting any claim of the patent is raised by the request and the prior art cited therein, with or without consideration of other patents or printed publications. A statement and any accompanying information submitted pursuant to § 1.501(a)(2) will not be considered by the examiner in the examiner's determination on the request. The examiner's determination will be based on the claims in effect at the time of the determination, will become a part of the official file of the patent, and will be mailed to the patent owner at the address provided for in § 1.33(c) and to the person requesting reexamination.

* * * * *

6. Section 1.552 is amended by adding new paragraph (d) to read as follows:

§ 1.552 Scope of reexamination in ex parte reexamination proceedings.

* * * * *

(d) Any statement of the patent owner and any accompanying information submitted pursuant to § 1.501(a)(2) which is of record in the patent being reexamined (which includes any reexamination files for the patent) may be used after a reexamination

proceeding has been ordered to determine the proper meaning of a patent claim when applying patents or printed publications.

Date: December 30, 2011_____

David J. Kappos
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

[FR Doc. 2011-33813 Filed 01/04/2012 at 8:45 am; Publication Date: 01/05/2012]